ABBOTT

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Abbott Park, Illinois 60064-3537

February 16, 2000

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

RE: CITIZEN PETITION
REQUEST FOR AN EXEMPTION

Abbott Laboratories herein submits four copies of this petition under 21 CFR 898.14 to request the Commissioner of Food and Drugs to exempt the device described below from the Performance Standard of 21 CFR part 898 Performance Standard For Electrode Lead Wires and Patient Cables (hereafter "Performance Standard").

It is the understanding of Abbott Laboratories that an exemption is not effective until the Agency approves the request under 21 CFR 10.30(e)(2)(i).

I. Description of Product(s).

This petition relates to the Abbott Laboratories catheter introduced RV Pacing Lead, List number 50345, which is a transluminal pacing lead indicated for temporary ventricular pacing only. This device is classified as a Class II device under 21 CFR 870.3680 and cleared under 510(k) number K962467 on September 17, 1996. Diagrams of the RV Pacing Lead and the RV Pacing Lead attached to a pacing equipment cable are located in Attachment A. Labeling and package insert in the form of instructions for use of the Abbott Laboratories RV Pacing Lead List number 50345 are included in Attachment B.

II. Use of the Abbott RV Pacing Lead

The Abbott transluminal RV Pacing lead is used to treat symptomatic heart block conditions that result in abnormal cardiac conduction, unstable cardiac rhythms that may progress to symptomatic heart block or as prophylaxis in clinical situations that have a finite risk of heart block based on concurrent interventions. Temporary pacing leads are used specifically with a pulmonary artery catheter. The method of use is as follows:

a) The Abbott transluminal RV Pacing lead is used only with a Thermodilution (Swan-Ganz) Catheter list number 41252 and 41300 or an Opticath® Pacing Catheter list number 50344

b) Verify catheter placement of Right Ventricular port

c) Connect catheter Right Ventricular hub to the lead adapter

d) Advance lead and position in catheter

e) Attach contamination sheath to adapter

f) Remove protective caps on lead connectors

g) Insert lead connectors into pacing equipment cable

h) Connect cable to pacing equipment

III. Reason Why Exemption from Performance Standard is Requested

In order to meet and be in compliance with the performance standard, requirements of subclause 56.3(c) of the international IEC 60601-1 must be satisfied. This requires that the connector meet three test requirements: (1) the conductive elements must not make contact with live parts of a mains socket, (2) the standard test finger must not make contact with the conductive elements of the connector and (3) the conductive elements of the connector must not be able to touch a flat surface. The Abbott RV Pacing Lead is less than 8 inches long (see attachment A) from the catheter attachment to the electrode lead. When attached to the patient, it cannot physically reach a mains outlet.

IV. Reasons That Mitigate The Risk

Temporary pacing leads are used in distinct areas of a hospital such as a sterile surgical suite, intensive care, cardiac catheterization lab and emergency treatment areas. There are usually no AC access mains in a sterile area. The personnel that would use these devices are highly trained professional clinicians who are not going to accidentally plug a pacing lead into a mains outlet. After the pacing lead has been introduced into the catheter, the remaining exposed segment of the lead is either inserted into an external pacemaker or a reusable cable which is then inserted into the pacing equipment. These medical devices are not used outside of a hospital. The following information applies to the Abbott RV Pacing lead:

1. The electrode connectors are covered with a plastic sheath that must be removed prior to use.

2. The individual connectors are labeled " WARNING do not plug the male pin connectors into a wall socket. Such use can result in serious injury or death to the patient or operator."
3. The pacing lead can not reach a mains outlet since it is less 8 inches long from the catheter adapter to the electrode connector.

4. Most of the cables provided by manufacturers that are used with the Abbott RV Pacing Lead have already been modified to meet IEC-601-1 subclause 56.3(c). Appended in Attachment A is an illustration of how the Abbott RV Pacing Lead would be attached to a Medtronic reusable cable.

IV Scope of Petition

Temporary pacing leads that have been cleared under 21 CFR 870.3680 have been used for many years without a reported injury to a patient or practitioner due to the incorrect placement of a pin connector into a mains or a power cable connected to a main. Additionally, the Medtronic Company has requested and received a similar exemption (see docket number 98P-0330) for a device that also has an electrode connector. Therefore, the applicant seeks an exemption for the Abbott Laboratories RV Pacing Lead list 50345 from the performance standard. We seek this exemption for our RV Pacing Lead that is used with the Abbott Thermodilution Catheter list numbers 41252 and 41300 as well as the Abbott Opticath® Pacing Catheter List 50344.

V. Environmental Impact

There is no environmental impact statement needed because the Petition, as an exemption from standard, is automatically exempt under 21 CFR 25.24(e)(3).

VI. Certification

The undersigned hereby certifies that in my capacity as Manager, Regulatory Affairs for Abbott Laboratories, Hospital Products Division that to the best of my knowledge this petition includes all information and views on which the petitioner relies and includes representative data and information know to the petitioner which are unfavorable to the petition.

Sincerely,

Abbott Laboratories

Thomas P. Sampogna

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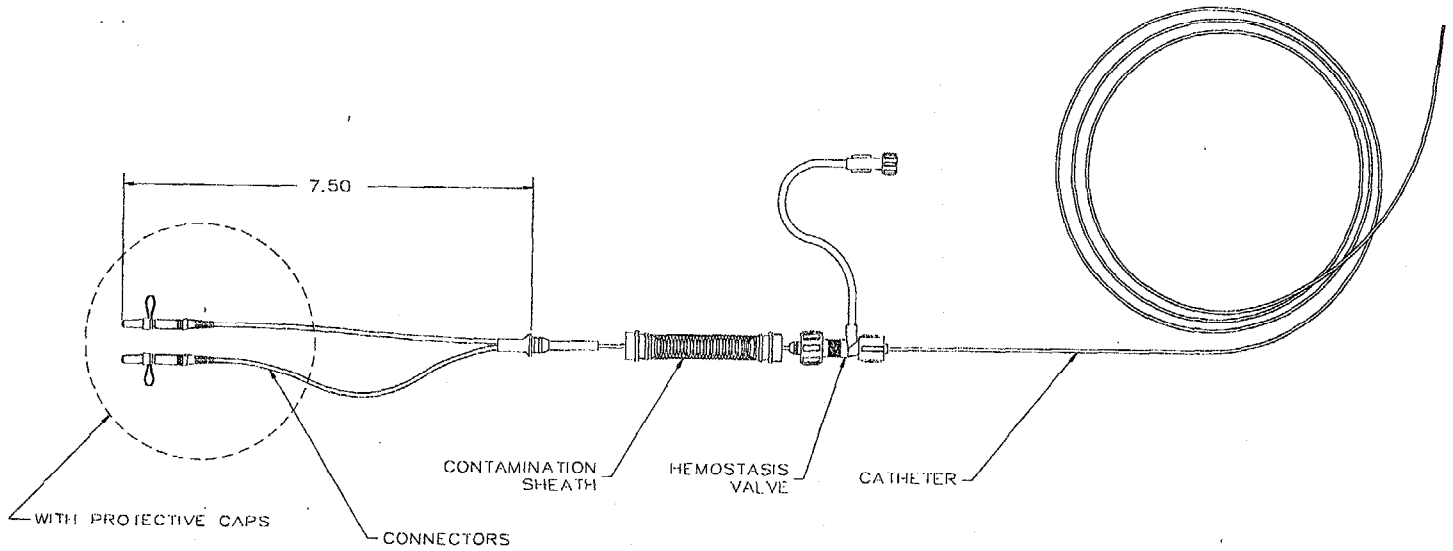
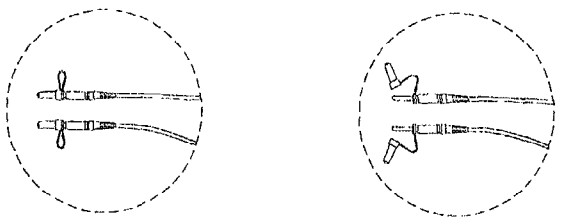
Attachment A
Diagrams of the RV Pacing Lead and the RV Pacing Lead attached to a pacing equipment cable

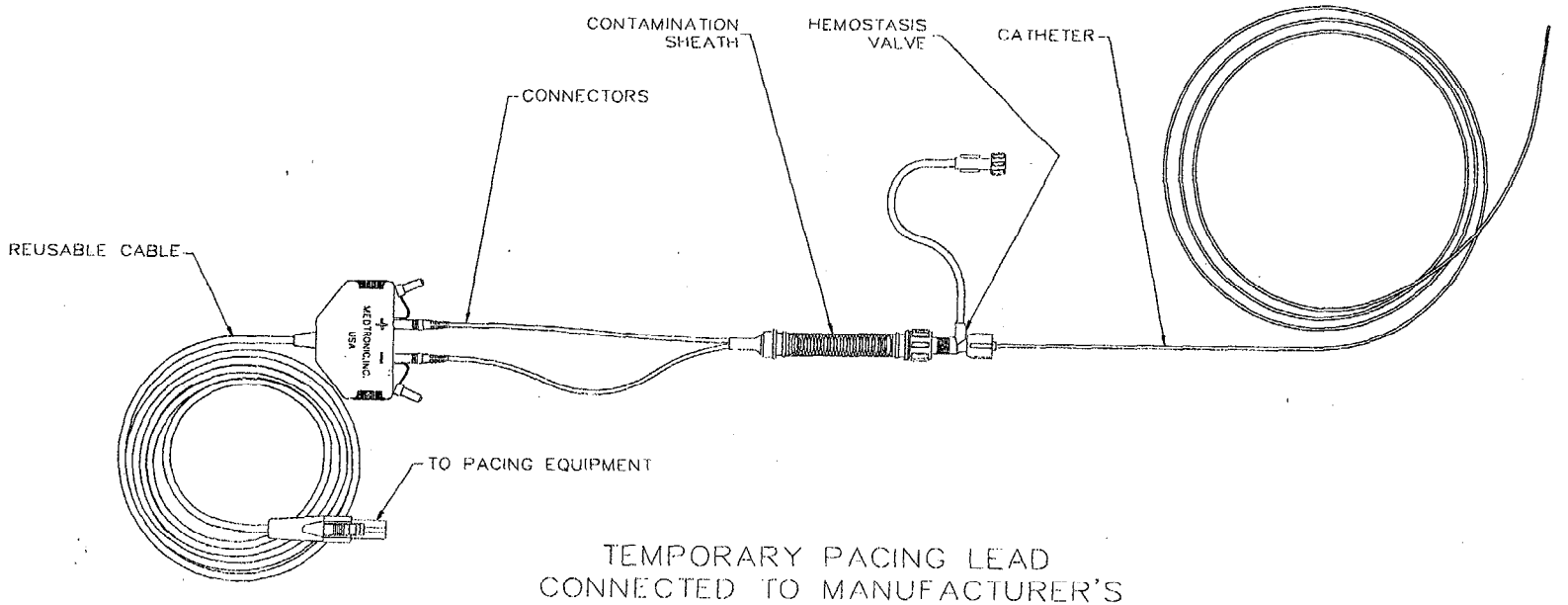
The Abbott transluminal RV pacing lead is a temporary pacing lead used only with thermodilution (Swan-Ganz) catheters, P/N 41252 and 41300 and Opticath®, P/N 50344. Prior to insertion, tethered insulating caps protect the electrical connectors of the pacing lead, as shown in the illustration. These caps are fixed via an interference fit.



Once the pacing lead is in place in the catheter, the insulating caps are removed and the connectors inserted into the reusable cable.

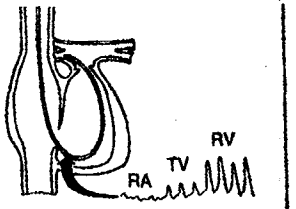


With the caps removed, the lead connectors are inserted into a reusable cable provided by the manufacturer of the pacing equipment. The pacing lead itself is too short to reach the pacing equipment. From the end of the connector to the hub of the contamination sheath is approximately 8 inches. The reusable cables provided by most manufacturers have already been modified to meet IEC 601-1 subclause 56.3(c). The illustration below shows our temporary lead, as it would connect to a Medtronic reusable cable.

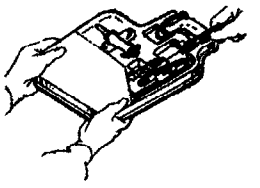


TEMPORARY PACING LEAD
CONNECTED TO MANUFACTURER'S
REUSABLE CABLE

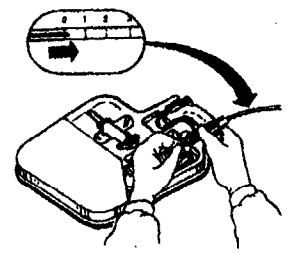
Attachment B
Labeling and package insert for the Abbott Laboratories RV Pacing Lead list number 50345



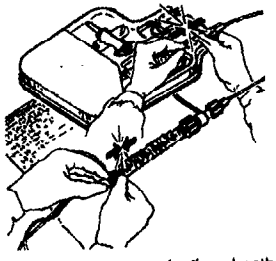
2 Verify proper placement of Right Ventricular port.



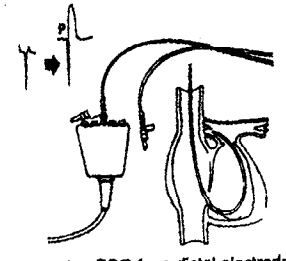
3 Connect Catheter RV lumen hub to Tuohy-Borst adapter.



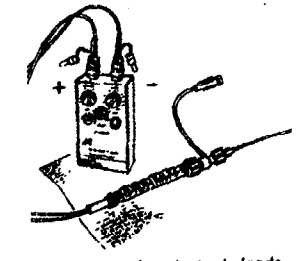
4 Advance lead and position in catheter.



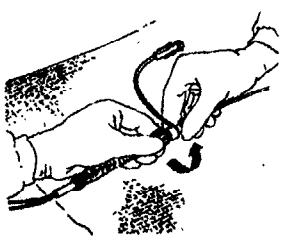
5 Attach lead contamination sheath to Tuohy-Borst adapter and probe.



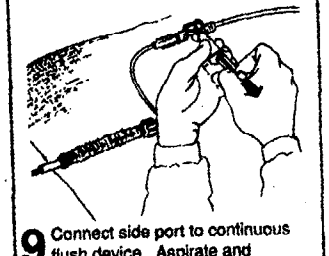
6 Monitor ECG from distal electrode while positioning lead.



7 Connect pacing electrode leads to external pacemaker.



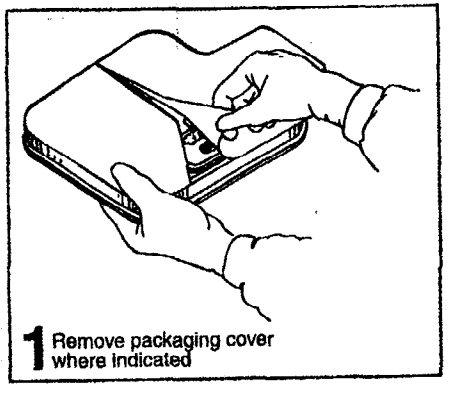
8 Secure pacing lead to Tuohy-Borst adapter.



9 Connect side port to continuous flush device. Aspirate and flush lumen.

NOTE: This cover does not constitute a sterile barrier.

31-1154



1 Remove packaging cover where indicated

SAMPLE

NOT FOR HUMAN USE

6/85-S3541

FOR DEMONSTRATION PURPOSES ONLY NOT FOR HUMAN USE

06-6849-R1-5/90

RV PACING LEAD

HEPARIN-COATED TRANSLUMINAL RV PACING LEAD FOR TEMPORARY VENTRICULAR PACING ONLY

LIST NO. 50345-03

This Product Contains Dry Natural Rubber.

RECOMMENDED FOR USE WITH:

ABBOTT CRITICAL CARE SYSTEMS THERMODILUTION CATHETER LIST NOS. 41252 and 41300

AND

OPTICATH® PACING CATHETER, LIST NO. 50344

ABBOTT
CRITICAL CARE SYSTEMS
Abbott Laboratories
North Chicago, IL 60064

50-6618-R1-7/98

WARRANTY

Abbott Laboratories warrants that reasonable care has been used in the manufacture of this product. THIS WARRANTY IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES NOT EXPRESSLY SET FORTH HEREIN, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS. SINCE HANDLING, STORAGE, CLEANING OR STERILIZATION OF THIS PRODUCT OTHER THAN BY ABBOTT AS WELL AS FACTORS RELATING TO THE PATIENT, HIS/HER DIAGNOSIS, TREATMENT, SURGICAL PROCEDURES AND OTHER MATTERS BEYOND ABBOTT'S CONTROL DIRECTLY AFFECT THIS PRODUCT AND THE RESULTS OBTAINED FROM ITS USE, ABBOTT SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM THE USE OF THIS PRODUCT OTHER THAN THE REPLACEMENT OF IT. ABBOTT NEITHER ASSUMES, NOR AUTHORIZES ANY OTHER PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS PRODUCT.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician or other licensed practitioner.

ABBOTT
CRITICAL
CARE
SYSTEMS
Abbott Laboratories
North Chicago, IL 60064

06-9579-R1-7/98

PRINTED IN U.S.A.

RV PACING LEAD

HEPARIN COATED TRANSLUMINAL RV PACING LEAD FOR TEMPORARY VENTRICULAR PACING ONLY

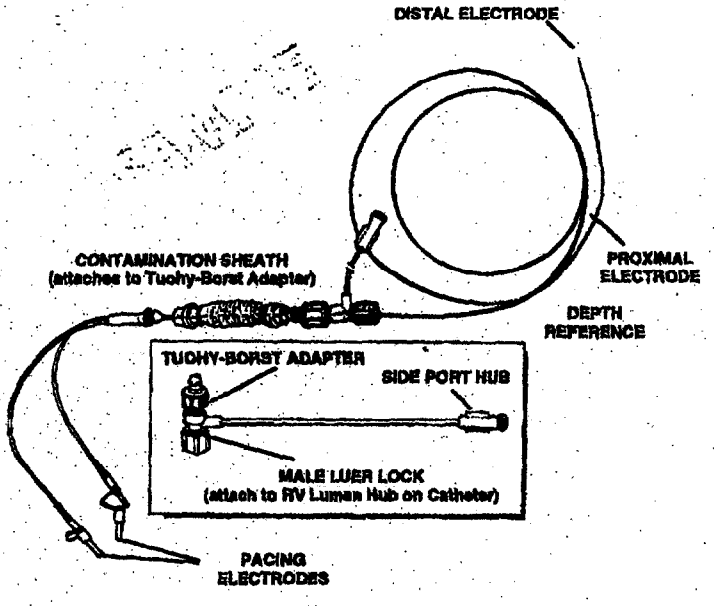
ABBOTT CRITICAL CARE SYSTEMS

LIST NO. 50345

This Product Contains Dry Natural Rubber.

For single patient use only.

This device should only be used by those trained in its use.



DESCRIPTION AND USE

The Abbott Critical Care Systems Transluminal Pacing Lead is intended for use in temporary right ventricular pacing, and can also be used for intraventricular ECG monitoring. It is a bipolar, coaxial, wire construction composed of stainless steel round wire and a TEFLON® coated, coiled flat wire. The lead's distal tip (15 cm) is coated with heparin.

When temporary transluminal pacing is indicated, the RV Pacing Lead should only be used with the Abbott Critical Care Systems Pacing Thermodilution Catheter (List Nos. 41252 and 41300) or Pacing OPTICATH® (List No. 50344). After the catheter is inserted and floated into the pulmonary artery with the right ventricular (RV) port properly placed 1 to 2 cm distal to the tricuspid valve, the pacing lead is inserted into the pacing catheter's RV lumen and advanced into the right ventricle for endocardial pacing.

NOTE: For specific instructions for insertion of the Abbott Critical Care Systems Pacing Thermodilution or OPTICATH Catheters, please refer to their packaging inserts.

CONTRAINDICATIONS

The lead is intended only for use with the Abbott Critical Care Systems Pacing Thermodilution or Pacing OPTICATH Catheters, and is intended for ventricular pacing only.

Heparin-coated catheters and leads should not be used on patients with known sensitivity to heparin. Pacing should not be done on patients with small hearts if the RV port of the pacing catheter cannot be placed into the right ventricle without spontaneously wedging the catheter in the pulmonary artery with the balloon deflated.

There are no absolute contraindications to the use of temporary endocardial pacing electrodes. However, patients with recurrent sepsis or with a hypercoagulable state, where a part of the catheter or the electrode could serve as a focus for septic or bland thrombus formation, should not be considered candidates for balloon flotation catheters or pacing leads.

LEAD SPECIFICATIONS

Usable length (cm)	
Total	135
In ventricle	15
Body diameter	2.3 F (0.030")
Electrodes	Stainless steel with pin connectors (0.080 inch diameter) at proximal end, with protective covers.
Distal:	
Length (cm)	1.8
Diameter (in.)	0.023
Proximal:	
Length (cm)	13.0
Diameter (in.)	0.023
Insulation between electrodes	Polyurethane elastomer, 1.5 cm long.
Special markings	White green length index at 114.0 cm
Lead labeling	
Distal	Black
Proximal	Red
Lead covers	Clear tethered insulating caps cover exposed electrical connections
Heparin coating	Distal 15 cm

STERILE ACCESSORIES SUPPLIED WITH LEAD

1. Hemostatic Tuohy-Borst adapter with side port
2. Syringe, 5cc
3. Contamination sheath

EQUIPMENT

1. Abbott Critical Care Systems Pacing TD or Pacing OPTICATH®
2. Abbott Critical Care Systems Transluminal Pacing Lead
3. Ventricular demand external pacemaker
4. ECG recorder
5. Pressure transducers and amplifiers
6. Strip-chart recorder or oscilloscope
7. Sterile heparinized flush system

In case of patient complications antiarrhythmic drugs, a defibrillator and respiratory assist equipment should be immediately available.

CATHETER INSERTION AND PLACEMENT

Insert the catheter either by cutdown or percutaneously through a jugular, subclavian, or antecubital vein; the use of the percutaneous method is recommended to minimize the possibility of bleeding at the entry site. INSERTION THROUGH A FEMORAL VEIN IS NOT RECOMMENDED.

Use two pressure transducers while inserting the catheter; connect one transducer to the distal (PA) lumen, the other to the right ventricular (RV) lumen. Continuously monitor both PA and RV lumen pressures while advancing the catheter into the pulmonary artery wedge position.

When the catheter tip is in the wedge position, location of the RV port will depend on heart size. The ideal placement of the RV port for lead placement is 1 to 2 cm distal to the tricuspid valve. A radiopaque marker located at the RV port will confirm port placement by x-ray or fluoroscopy.

1. **NORMAL SIZE HEARTS**

   In the wedge position, the RV lumen shows RV tracing. Deflate the balloon, and pull the catheter back until the RV port is in the right atrium. Then readvance the catheter until the port is 1 to 2 cm distal to the tricuspid valve.

2. **SMALL HEARTS**

   In the wedge position, the RV lumen shows a right atrial (RA) pressure tracing. Deflate the balloon, and advance the catheter slowly while closely monitoring the PA and RV lumen pressures until an RV pressure tracing is obtained from the RV lumen. Then advance the catheter 1 to 2 cm distal to the tricuspid valve.

   If the RV port is in the right ventricle while the catheter tip is spontaneously wedged, reposition the catheter to properly position the lead. Advance the lead a centimeter at a time into the right ventricle while withdrawing the catheter a centimeter at a time back into the right atrium until a continuous pulmonary artery pressure tracing is seen.

   NOTE: Make sure the RV port is in the ventricle before inserting the lead. Insertion of the lead with RV port in the right atrium may damage the tricuspid valve.

   If the catheter spontaneously wedges with the balloon deflated before the RV port can be positioned in the right ventricle, discontinue attempts to position the lead. The pacing system should not be used; however, the catheter can still be used for pressure monitoring, blood sampling, fluid infusion and cardiac output determinations.

3. **ENLARGED HEARTS**

   If the RV lumen shows an RV pressure tracing before wedge position has been reached, continue to advance the catheter until a wedge pressure is registered. Deflate the balloon and withdraw the catheter until a right atrial pressure tracing is seen from the proximal lumen. Readvance the catheter until the RV port is 1 to 2 cm distal to the tricuspid valve.

   NOTE: In this position the catheter tip should be in the pulmonary artery, and it may not be possible to obtain capture and wedge pressure measurements simultaneously.

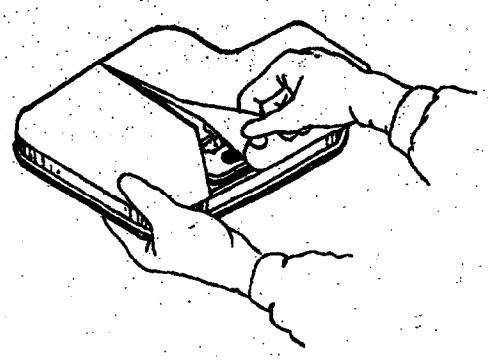
   WARNING: If the RV port is too distal, the probe may exit the RV port pointed in the direction of the RV outflow tract. This may result in poor thresholds, unstable pacing, and potential damage to the outflow tract and pulmonic valve.

PACING LEAD INSERTION AND PLACEMENT

Use sterile technique while handling the lead, and be careful to insert the lead only into the RV lumen, identified by the clear extension tubing and orange luer connector. To facilitate lead insertion, make sure the portion of the catheter remaining outside the patient is straight.

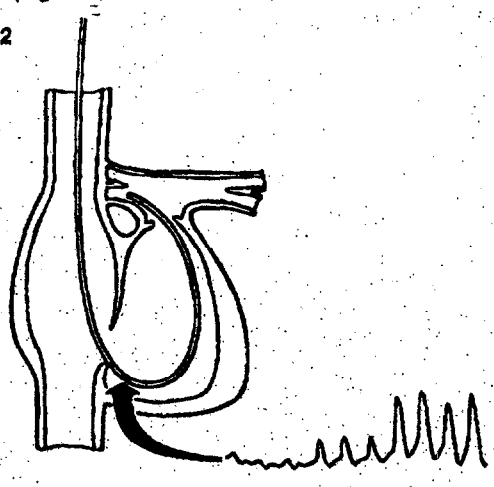
1. Flush the RV lumen with sterile solution to ensure patency.
2. Remove package cover where indicated. (Figure 1)

FIGURE 1



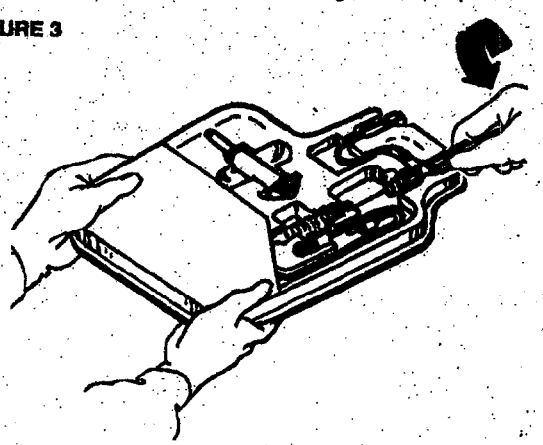
3. Connect the catheter RV lumen hub to a pressure transducer and verify proper placement of the RV port 1 to 2 cm distal of the tricuspid valve. (Figure 2)

FIGURE 2



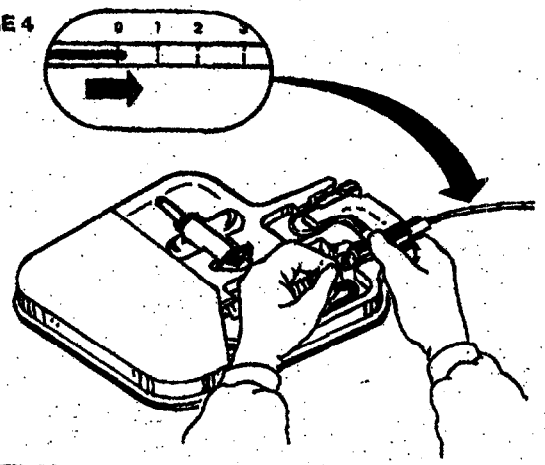
4. Disconnect the catheter RV lumen from the pressure transducer. Remove the protective cap from the male luer of the Touhy-Borst (T-B) adapter and connect the T-B adapter to the RV lumen hub (Figure 3), taking care not to damage the lead tip.

FIGURE 3



5. Advance the lead until its depth reference mark (color transition from green to white) is placed at the zero mark on the clear extension tube of the RV lumen (Figure 4). This will place the tip of the lead approximately 2 cm from the RV port within the RV lumen.

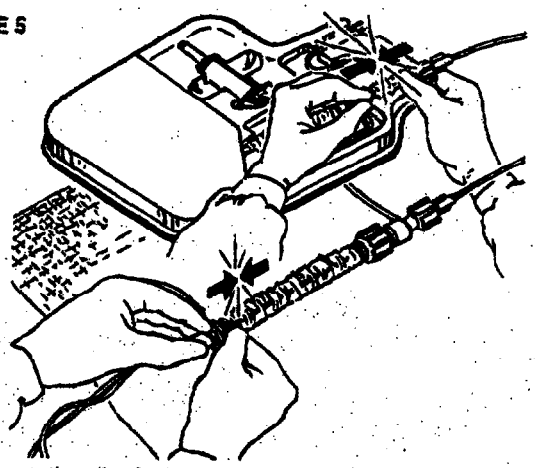
FIGURE 4



NOTE: The lead may encounter resistance as it passes through the hemostasis valve of the introducer and the curves in the catheter, and at the RV port. Resistance at any other point may indicate that the catheter is kinked. Do not force the lead if resistance is met.

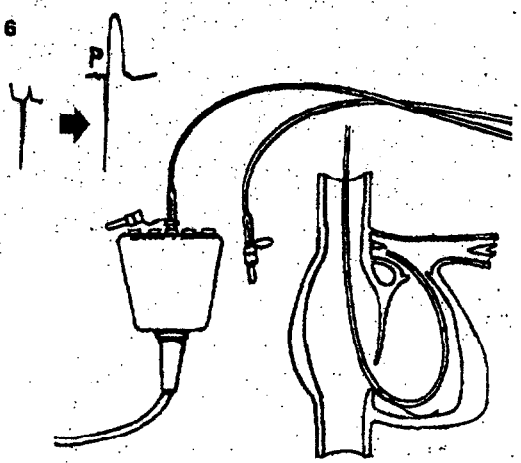
6. Attach the distal end of the lead contamination sheath to the T-B adapter and the other end to the proximal end of the lead (Figure 5). The lead is now ready to be advanced into the RV.

FIGURE 5



7. Connect the distal electrode to a V lead of a properly isolated electrocardiograph (Figure 6). While monitoring ECG, advance the lead several centimeters until ST segment elevation of the ECG indicates contact with the endocardium.

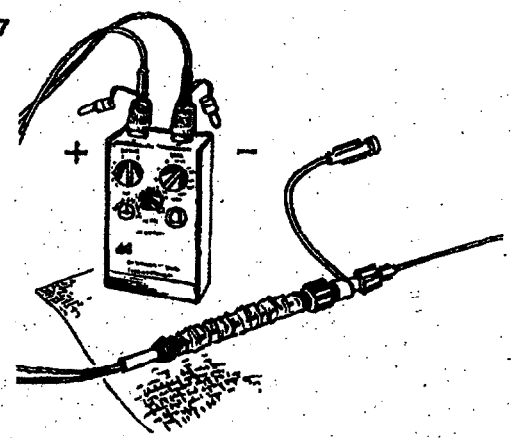
FIGURE 6



NOTE: ST elevation occurs when the lead has made good contact with the endocardium—usually when the lead is extended 4 to 5 cm—although an adequate pacing threshold may be achieved without sensing the ST segment elevation during lead placement. If the lead is out more than 10 cm, it may be in the RV outflow tract. Retract the lead back to 4 to 5 cm and reposition in the RV apex.

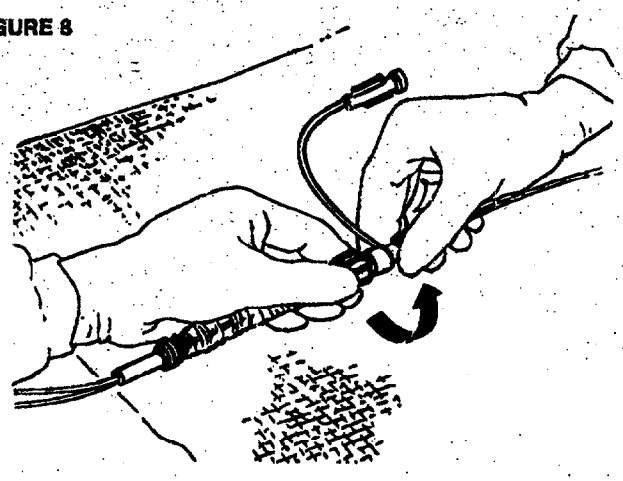
8. Connect the distal and proximal pacing leads to the negative and positive pacemaker terminals, respectively. (Figure 7) Proper electrode placement at approximately 5 cm out of the RV port results in pacing thresholds of 2.0 mA. Unstable pacing may occur if the lead is positioned less than 3 cm out of the RV port. A pacing threshold of greater than 5.0 mA indicates improper placement of the pacing lead; to correct placement, withdraw the lead several centimeters and reposition.

FIGURE 7



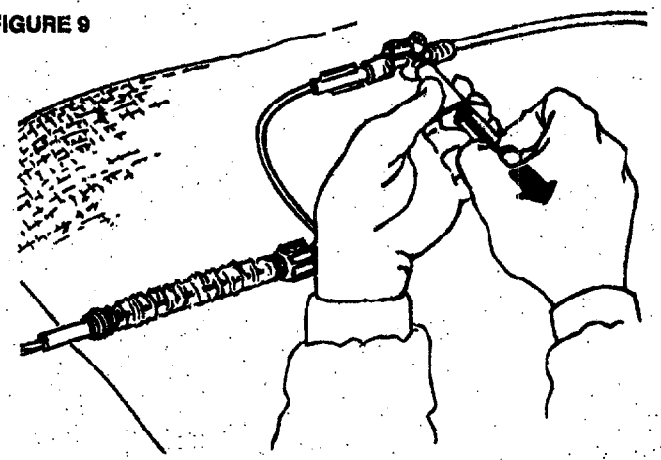
9. Tighten the T-B adapter to secure the pacing lead in place (Figure 8).

FIGURE 8



10. Using a 3-way stopcock, connect the side port of the T-B adapter to a continuous heparinized saline flush device. Using the 5 cc syringe provided, aspirate any air from the side port and flush the lumen. (Figure 9)

FIGURE 9



NOTE: When the probe is in the RV lumen, do not infuse solution at a rate greater than 30 mL/hr because the solution may back up into the contamination sheath.

COMPLICATIONS

1. LOSS OF CAPTURE, caused by patient movement or other inadvertent dislodgment of the lead from contact with the endocardium. Poor initial lead placement will increase the possibility of dislodgment. If the patient has moved, place the patient in a supine position and increase the pacing threshold, repositioning the lead if necessary. Myocardial perforation, although unlikely, may also result in loss of capture; regain by repositioning the lead in the ventricular apex.
2. TRANSIENT MULTIFOCAL PVCs or V-Tach, due to endocardial irritation by the lead tip. Advance the lead or manipulate the catheter to correct the problem; if not successful, pull the catheter back 1 to 2 centimeters, verify its position by waveform or fluoroscopy, and readvance the lead.
3. DIFFICULTY ACHIEVING WEDGE PRESSURES when the balloon is inflated, especially in enlarged hearts where the catheter is pulled back from the initial wedge position. Monitor PA diastolic pressure rather than wedge pressure, if possible. If wedge pressure is required and pacing is no longer needed, turn off the pacemaker, withdraw the lead into the catheter, and advance the catheter until a wedge pressure is obtained.
4. INADVERTENT ATRIAL PACING, if the RV port is initially positioned in the atrium or if the catheter or lead withdraws into the right atrium. Withdraw the lead tip into the catheter and reposition the RV port 1 to 2 centimeters beyond the tricuspid valve. Reposition the lead in the ventricular apex.
5. INADEQUATE SENSING of the demand pacemaker, if the pacing lead is not positioned properly in the ventricle. Careful repositioning may correct this problem.
6. VENTRICULAR PERFORATION with transluminal pacing leads can result in intermittent or unsuccessful pacing. To diagnose a perforation, connect the distal electrode of the pacing lead to the V-lead of a battery powered electrocardiograph. As the pacing lead is withdrawn and moves into the myocardial wall, the ECG shows ST segment elevation with T-wave inversion, and is often accompanied by ectopic ventricular beats. When the electrode reaches the right ventricular chamber, a prominently negative R-wave appears. Cardiac tamponade may occur in rare instances. Manipulation of the heart with the pacing lead extended into the ventricle increases the possibility of endocardial perforation. Caution should therefore be taken or the lead withdrawn during manipulation of the heart. Diaphragmatic pacing "hiccups" or diaphragmatic stimulation synchronous with pacing is often indicative of ventricular perforation by pacing lead.

HOW SUPPLIED

The Abbott Critical Care System Pacing Lead is supplied sterile and nonpyrogenic only if the package is unopened and undamaged. If accidentally contaminated before use, do not resterilize.

STORAGE/SHELF LIFE

Store the leads in their individual shipping boxes in a cool area free from exposure to light, dampness, and chemical fumes. Recommended shelf life is indicated on each catheter package by the "EXP. DATE." Resterilization will not extend shelf life.

REFERENCES

Bern, A.I., Pane, G.A., and Hamilton, G.C.: Electrical Interventions in Cardiopulmonary Resuscitation: Pacing. Symposium on Resuscitation. Emergency Medicine Clinics of North America, 1:541-552, 1983.

Donovan, K.D., and Lee, K.Y.: Indications for and Complications of Temporary Transvenous Cardiac Pacing. Anesthesia and Intensive Care 13:63-70, 1985.

Finkelmeier, B.A., and O'Mara, S.R.: Temporary Pacing in the Cardiac Surgical Patient. Critical Care Nurse Jan/Feb:108-114, 1984.

Gessler, C.J., and Jaffe, A.S.: Hemodynamic Monitoring and Pacing with One Catheter: A Pilot Study. Catheterization and Cardiovascular Diagnosis 13:141-144, 1987.

Haffajee, C.I.: Temporary Cardiac Pacing: Modes, Evaluation of Function, Equipment, and Trouble Shooting. Cardiology Clinics 3:515-526, 1985.

Hauser, R.G., and Vicari, R.M.: "Temporary Pacing - Indications, Modes and Techniques." Medical Clinics of North America 70:813-827, 1986.

Mora, C.T., Seltzer, J.L., and McNulty, S.E.: "Evaluation of a New Design Pulmonary Artery Catheter for Intraoperative Ventricular Pacing." Journal of Cardiothoracic Anesthesia 2:303-308, 1988.

Parsonnet, V., and Bernstein, A.D.: "Pacing in Perspective: Concepts and Controversies." Circulation 73:1087-1093, 1986.

Zaiden, J.R.: "Pacemakers." Anesthesiology 60:319-334, 1984.

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